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Preliminary feasibility and value of home fertility testing for men with cystic fibrosis

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Background: An estimated 98% of men with cystic fibrosis (CF) are infertile because of congenital absence of the vas deferens [1], although most studies were conducted before wide recognition of milder genotypes and phenotypes. Limited data suggest that infertility rates may vary according to genotype [1,2]. Semen analysis is indicated for all men with CF [3], but barriers include pressing care needs, that some labs do not process semen, and that referrals may burden patients. The Food and Drug Administration–approved SpermCheck Fertility Home Test for Men is 96% accurate at detecting normal sperm count (>20 000 000 sperm/mL). This rapid qualitative immunodiagnostic test detects sperm using antibodies against sperm acrosome-specific protein analyte SP10. At-home semen analysis may be a valuable, feasible, cost-effective (\$25/test) option for men with CF. This descriptive study aimed to assess feasibility and patient perceptions.

Methods: Men with CF who completed an online fertility survey were invited to receive a test kit and complete an interview about ease of use, interpretation, perceived accuracy and benefit, and feelings about results. With permission, interviews were recorded and transcribed; descriptive results are presented.

Results: Four men participated (Table 1). All had negative test results consistent with CF-related infertility. All found following instructions and reading results to be easy, believed results were accurate, and felt this type of test would be helpful to the CF community. None intended to alter family plans based on results. Several expressed relief that assumed infertility was confirmed. Descriptive feedback included:

P1: “It’s nice to officially know. I guess there’s less doubt in my head, like, “well, you know, I technically don’t know.” So now I believe it. For what it’s worth I thought I had to go to a professional agency to get this done. Had I known this was so affordable and I could do it from home I probably would have done it back in my early 20 s.”

P2: “I mean, I kind of expected the results that I got, but at the same time, it made me feel sad for a few seconds. Like the realization of it, but then like... ehh, well, I expected it.”

P3: “I’m married... I had a pretty good idea I wasn’t fertile, but it’s good to have information on stuff and be able to pass information along.”

P4: “I think it’s just a way to confirm things. Because, you know, within clinic and stuff they talk about it but there’s no real way of testing. They don’t give you any options as far as how to test certain things.”

Conclusions: These perspectives support continued investigation of home fertility tests for men with CF. Formal qualitative analysis was not completed because the number of participants was small. Future directions include a larger study, results correlation with conventional semen analysis and patient genotypes, and potential use of the SpermCheck Vasectomy kit, which detects lower sperm concentration (250 000 sperm/mL). Such tests may contribute to modern fertility insights and improve patient care.

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Using continuous glucose monitoring to predict disease progression and development of diabetes in youth with cystic fibrosis

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Background: Cystic fibrosis (CF)-related diabetes (CFRD) is one of the most common complications of CF and is associated with undernutrition, poor pulmonary function, and mortality. Clinical decline has been described up to 5 years before the diagnosis of CFRD and may be related to early dysglycemia. Continuous glucose monitoring (CGM) can detect early glucose abnormalities before they develop during a 2-hour oral glucose tolerance test, but no clear CGM based cut-points for predicting clinical decline in people with CF have been defined. Our aim was to explore CGM as a tool for prospectively predicting CF-relevant clinical outcomes in youth with CF.

Methods: This was a single-center, prospective analysis of data collected as part of the GlycEmic Monitoring in CF (GEM-CF) Study. Participants were aged 6 and older, diagnosed with CF, and followed at Children’s Hospital of Colorado CF Center. Participants wore a CGM (iPro[®]2) between 2014 and 2018. Participants with diagnoses of CFRD taking insulin or other medications affecting glucose metabolism at time of CGM wear were excluded from this analysis. Information on the following variables was collected at baseline (time of CGM wear) and prospectively through early 2020: forced expiratory volume in 1 second (FEV₁), forced vital capacity (FVC), body mass index z-score (BMI-z), time to diagnosis of CFRD, and time to insulin start. Mixed-effects models were used to test association between baseline CGM variables and change in BMI-z, FEV₁ percentage predicted (FEV₁pp), and FVC percentage predicted (FVCpp) over 1 and 3 years. Cox proportional hazards models were used to test the associations between baseline CGM variables and time to diagnosis of CFRD and time to insulin start.

Results: Seventy-five individuals with CF were included. Baseline age was 13.36 ± 3.48 years, 42 (56%) participants were female, and five (6.7%) were pancreatic sufficient. Baseline mean BMI-z was -0.04 ± 0.80, mean FEV₁pp was 95.9 ± 14.7%, and mean FVCpp was 102.7 ± 13.2%. Mean ± SD for the following CGM variables were average sensor glucose, 112 ± 15 mg/dL; percentage of time spent at greater than 140 mg/dL, 13.1 ± 13.2%;

Table 1 (abstract 11):
Participant characteristics

Table 1. Participant Characteristics						
Participant	Age	Race	Genotype	Pancreatic Insufficient	Modulator	Prior semen analysis
1	29	Caucasian	F508del, not reported	N	Y	N
2	39	Caucasian	F508del homozygous	Y	Y	N
3	24	Caucasian	F508del homozygous	Y	Y	N
4	25	Caucasian	F508del, 2789+5G>A	N	Y	N